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EXAMINER
STANTON, B

ART UNIT	PAPER NUMBER
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DATE MAILED: 03/25/96

This is a communication from the examiner in charge of your application.
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For Restriction Purposes Only

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire ~~0~~ month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1 - 58 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☐ Claims _____ are rejected.

5. ☐ Claims _____ are objected to.

6. ☑ Claims 1-58 are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Claims 1-58 are pending in the instant Application.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-17, drawn to nucleic acids encoding cdn, and associated vectors and host cells, classified in Class 536, subclass 24.1, and Class 435, subclasses 320.1, 240.2, and 283.

Group II. Claims 18-22, drawn to transgenic animals comprising cdn nucleotide sequences, classified in Class 800, subclass 2.

Group III. Claims 23-31, drawn to cdn proteins, classified in Class 530, subclass 350.

Group IV. Claim 32-38, drawn to anti-cdn antibodies and methods of using said antibodies, classified in Class 530, subclass 387.1, and Class 435, subclass 7.1.

Group V. Claims 39-41, 43, and 44, drawn to hybridization assays, classified in Class 435, subclass 6.

Group VI. Claims 42 and 45-52, drawn to gene therapy methods of modulating apoptosis, classified in Class 514, subclass 44 and Class 424, subclass 93.21.

Group VII. Claims 53-58, drawn to protein therapy methods, classified in Class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-IV are distinct, each from the other, because they are drawn to materially different compositions each of which requires distinct areas of search and consideration. For example, the nucleic acids of the invention of group I requires search of nucleotide sequences, and means of expressing nucleic acids encoding proteins. The invention of group II requires search and consideration of means of preparing transgenic animals and the effect that genetic modification of animals would have on the phenotype of such animals. Such consideration is not required for any of the inventions of groups I, III or IV. The proteins of the invention of group III require search and consideration of protein sequences and protein activities and may be prepared by direct isolation or chemical synthesis which does not require search or consideration of any of the inventions of groups I, II, or IV. The antibodies of the invention of group IV require search of antibody compositions and methods of preparing and using such antibodies. These considerations are not required for any of the inventions of groups I-III.

Inventions I and either of the inventions of group V or VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or

(2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids of the invention of group I may be used in materially different manners as evidenced by their use in the methods of groups V and VI..

Any of the compositions of groups I, II, or IV, are distinct from the invention of group VII because the latter invention utilizes protein therapeutics and therefore consideration of such proteins is required. None of the inventions of groups I, II, or IV, requires such consideration.

The inventions of any of groups II-IV are distinct from the methods of groups V and VI because said methods do not use any of the compositions of groups II-IV and therefore analysis of said methods does not require analysis of said compositions *per se*.

Inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the proteins of the invention of group III may be used to prepare antibodies or in *in vitro* assays.

The methods of group V are distinct from either of the methods of groups VI or VII because the latter methods involve *in vivo* administrations and alternation of host animals and therefore search and consideration of *in vivo* methods are required for analysis of the latter inventions. Such analysis is not required for consideration of the *in vitro* methods of the invention of group V.

The methods of groups VI and VII are distinct, each from the other because they utilize distinct therapeutic agents each of which requires separate areas of search and consideration. For example, the use of nucleic acid therapeutics (group VI) requires analysis of means of regulating nucleic acid gene expression *in vivo*, and of targeting nucleic acid gene expression to appropriate cells within a host. Such considerations are not required for search or consideration of protein therapeutic agents.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their divergent classifications and recognized divergent subject matter and because the searches required for the separate inventions are not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Stanton whose telephone number is (703) 308-2801. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Stone can be reached on (703) 308-3153. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1096.

Brian R. Stanton, Ph.D.
21 March 1996

BRIAN R. STANTON
PATENT EXAMINER
GROUP 1800